FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

MARGARET HALTON PRIEST,	§	
Individually and as Representative	§	
of the Estate of	§	
NOEL LAJOIE PRIEST	§	
	§	
Plaintiff,	§	
	§	
vs.	§	CAUSE NO.: 1:15-cv-00822-LY
	§	
	§	
SANDOZ INC.	§	
	§	
Defendant.	§	

FIRST AMENDED COMPLAINT

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW **MARGARET HALTON PRIEST, INDIVIDUALLY AND AS REPRESENTATIVE OF THE ESTATE OF NOEL LAJOIE PRIEST,** hereinafter the "Plaintiff" complaining of Defendant Sandoz Inc., and for cause of action would show the Court the following:

I. Introduction & Nature of Action

1. Deceased, Noel Lajoie Priest (Noel Priest), is an individual who resided in Texas. This suit is brought on behalf of the estate of Noel Priest by the Representative of his estate Margaret Halton Priest (Margaret Priest), and on behalf of the Margaret Priest, who resides in Texas, in her individual capacity. Noel Priest was prescribed, purchased, and ingested the drug Amiodarone (described more fully herein), which was manufactured and/or sold or distributed by

Defendant, and which proximately caused severe and debilitating injuries to Noel Priest's pulmonary system, resulting in his slow and painful death as a result of taking said drug, and hereby files this complaint as a result of Defendant's wrongful conduct.

2. Noel Priest suffered from Amiodarone toxicity induced pulmonary fibrosis lung disease and death as the direct result of consuming a product, Amiodarone, which was manufactured, supplied, sold, and distributed by the Defendant.

3. Prescription and medical records confirm that Noel Priest consumed Amiodarone.

4. Defendant's scheme in the past involved and continues to involve a calculated and deceitful sales campaign, and equally egregious failure and refusal to take required, timely, and accurate corrective actions and notice to medical professionals to prevent catastrophic injury and death to its customers, such as Noel Priest.

5. Defendant, like many other drug companies, spends billions of dollars each year trying to persuade doctors to prescribe their particular drugs. There are, however, strict FDA regulations about the form and content of such promotion. In fact, it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.[1]

6. The purpose of this federal regulatory requirement is to protect patients by ensuring that drug manufacturers will subject prospective uses of their drugs to randomized and well-controlled clinical trials to determine whether the drugs are safe and effective for such uses, at least where sufficient promise lies to make the cost of trials worth incurring. These requirements are meant to ensure that drug companies like Defendant give physicians and medical personnel trustworthy information, so that medications are prescribed appropriately.

[1] 21 U.S.C. §§ 331(d), 352 (f), and 355.

7. A manufacturer's duty to test a use arises, under both common law and federal law, when the manufacturer, such as the Defendant, learns of any adverse events concerning its sale of Amiodarone.

8. As described in further detail herein, in 1985, the initial manufacturer and distributer in the United States, Wyeth Ayerst Laboratories, Inc. ("Wyeth"), received FDA approval to market and sell Amiodarone only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies.[2]

9. After Wyeth received FDA approval, however, some companies, such as Defendant, and its hired agents, embarked on a course of conduct, the purpose of which was to increase Amiodarone sales as an initial, first-line anti-arrhythmic medication, for which Amiodarone has never received FDA approval, i.e., an "off-label" use.

10. The Amiodarone manufacturers and suppliers knew of the extreme dangers and catastrophic injuries and death caused by Amiodarone. They knew because of their receipt of adverse events reporting, customer and physician communications, and other sources. This history of Amiodarone's off-label marketing and its extreme danger were well known by the time that Defendant entered the market to manufacture, market, and distribute Amiodarone.

11. Upon information and belief, Defendant recognized a significant profit potential in the dangerous off-label promotion and sale of Amiodarone as a first-choice cardiac drug for non-life threatening heart ailments.

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[2] *See* NDA 18-972, Approval Letter, December 24, 1985.

12. Defendant tracked and had full knowledge of the number of prescriptions written for Amiodarone to be given as a first-line cardiac drug, and has, through various means designed to conceal Defendant's involvement, promoted and conspired together and with others to promote the use of Amiodarone as an initial, first-line therapy for arrhythmia and other heart ailments. Defendant and other manufacturers of Amiodarone decided to avoid the normal regulatory process of the FDA pertaining to the marketing of a new use of a drug and to proceed in illegal fashion. The decision was also made to actively conceal the illegal means that would be used to market the drug.

13. Defendant's scheme was implemented so that Defendant could tap into the enormous market for Amiodarone in the United States; a market created by Defendant's and other manufacturers' promotion of Amiodarone's off-label use. Defendant could both "free-ride" off of the millions spent by Wyeth and other manufacturers in promoting the dangerous off-label use of Amiodarone, and could promote it itself, all without spending the significant funds needed to obtain an FDA license for this dangerous use.

14. Upon information and belief, and at all material times hereto, Defendant was aware from multiple sources that many, possibly a majority, of Defendant's Amiodarone prescription sales were, and are currently, written for off-label purposes.

15. Defendant's scheme, described in more detail below, ultimately deceived physicians, pharmacists, and consumers into believing that prescribing and taking Amiodarone for the off-label uses that Defendant and others promoted was appropriate, even though Defendant knew that FDA approval had not been granted for those uses and, moreover, that there was significant medical-scientific evidence suggesting Amiodarone was very dangerous in those situations, and in fact resulted in serious pulmonary illness and toxicity, and death, when so used.

16. Finally, as described below, because of the toxicity of Amiodarone, and because of the years that Wyeth, Sandoz and other manufacturers spent promoting its off-label use, the FDA requires Amiodarone manufacturers to provide each patient with a Medication Guide – a "plain English" description of the dangers of a drug. Defendant failed to provide a Medication Guide to the pharmacy from whom Noel Priest obtained Defendant's Amiodarone, and because of this Noel Priest was killed by the drug.

II.
PARTIES

17. Plaintiff, is an individual who resides in Texas.

18. Defendant Sandoz is a New Jersey corporation with a principal place of business in Princeton, New Jersey. Defendant conducts substantial, systematic, continuous, and regular business in Texas. Defendant was involved in the distribution, marketing, sale, labeling, and design, of Amiodarone in the State of Texas and throughout the United States as detailed below.

19. At all material times, upon information and belief, Defendant authorized and/or acted by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendant.

20. At all material times, every reference made to Defendant in this First Amended Complaint includes predecessors, successors, parents, subsidiary, affiliates, and divisions of the corporation for the corresponding time period.

21. Whenever reference is made to any act, deed, or transaction of Defendant, the allegation means that the corporation engaged in the act, deed, or transaction by or through its officers, directors, agents, employees, or representatives while they were actively engaged in the

corporation's management, direction, control, or business affairs. If Defendant is a subsidiary of a foreign parent, then upon information and belief Defendant acted as its parent company's agent for its parent's U.S. sales.

III.
JURISDICTION & VENUE

22. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

23. Venue is proper pursuant to §28 U.S.C. §81 and §91 because a substantial part of the events or omissions giving rise to the claim occurred within the Western District of Texas, or Defendant conducts business in the Western District of Texas and the Austin Division. Defendant's commercial activities in the district and division include, but are not limited to, the marketing, sale and distribution of, and their generic equivalent, Amiodarone.

IV.
FACTUAL BACKGROUND

A. The Standard FDA Approval Process Was Not Required for Amiodarone, but Its Use Was Strictly Proscribed

24. All prescription drugs require approval by the U.S. Food and Drug Administration (hereinafter "FDA") before the drug may be marketed. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about

the drug's safety and efficiency gleaned from clinical trials.[3] It must also propose a label reflecting appropriate use, warnings, precautions, and adverse reactions.[4]

25. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the FDCA and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an "abbreviated new drug application" (hereinafter "ANDA") procedure for generic manufacturers.[5] Under the ANDA procedure, generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers. Rather, ANDAs are approved based on the initial safety profile of the name brand drug and are subject to all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug.

26. In 1985, Wyeth FDA approval to market and sell the anti-arrhythmic heart medication Cordarone® (amiodarone hydrochloride is the generic formulation) under a special "needs" approval, without the usually mandated rigorous and FDA approved, randomized clinical trials.[6] Although the FDA has urged Wyeth to conduct randomized clinical trials on its name-brand Amiodarone, such trials have not been conducted, presumably due to cost. The FDA's approval of Cordarone® remains a special and unusual "special needs" approval. The customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted. Wyeth was the initial manufacturer and distributor or "brand manufacturer" of Cordarone® in the United States.

[3] 21 U.S.C. § 355(a)-(b).
[4] 21 C.F.R. § 201.56
[5] 21 U.S.C. § 355(j).
[6] *See* NDA 18-972, Approval Letter, December 24, 1985.

27. Under the FDA's "special needs" approval, Wyeth's Cordarone® was approved as a drug ***of last resort*** for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia, but only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Wyeth also aggressively and successfully marketed Cordarone® for "off-label" uses as a "first line anti-arrhythmic therapy," which was completely contrary to the uses approved by the FDA in light of the drug's dangers.

B. Amiodarone Did Not Undergo The Rigorous FDA Approval Process Required For Federal Preemption

28. As noted above, on or about December 24, 1985, drug manufacturer Wyeth introduced Cordarone® into the United States stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Furthermore, despite repeated requests by the FDA at the outset of the approval process and throughout the history of the drug, neither Wyeth, Upsher-Smith the maker of the "other" brand name version of Amiodarone or the generic drug manufacturers of the product have submitted the drug to the rigorous randomized clinical trials required for FDA drug approval.

29. Amiodarone as the drug is commonly known was developed in Belgium in the 1960s as a drug for treating a common heart condition known as angina. At that time, Amiodarone was released for marketing in most countries ***other*** than the United States.

30. Use of Amiodarone as a drug "with little side effects" became widespread except in the United States. In the 1970s American Doctors began obtaining Amiodarone from Canada

and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA on a limited basis. Initial results were promising and by the mid-1980s literally tens of thousands of Americans were taking the drug without FDA approval or testing. American doctors apparently monitored the conditions of their patients more rigorously than their colleagues around the world because they found the drug produced a bizarre series of side effects that doctors around the world seemed to have missed and that were not caught because of the lack of testing or randomized trials.

31. The FDA was essentially forced to release Amiodarone for marketing in the United States by the mid-1980s when foreign manufacturers of the drug threatened to cut off the supply to Americans after having supplied the drug for free to thousands of Americans for over five years. American doctors convinced the FDA this would result in a medical disaster.

32. As a result, unlike any other drug in modern history, Amiodarone became FDA approved without rigorous, FDA sanctioned randomized clinical trials. The legal reasons for preemption applied to drug litigation for FDA approved drugs are not present in Amiodarone.

33. Amiodarone has been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness. Amiodarone is literally "stored" in most of the tissues of the body and to "load" the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of Amiodarone is to use extremely large dosages of the drug for the first week to two weeks then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg dosage a day when starting the drug and to maintain the patient on as little as100 to 200 mg per day on a chronic basis.

34. Amiodarone leaves the body slowly. The drug is not excreted like most drugs through the liver or kidney but is only lost when Amiodarone-containing cells such as skin cells or cells from the GI tract are lost. Therefore, even when it is decided that the patient needs to stop taking Amiodarone the drug remains in the system in measurable quantities for months.

35. Maybe most importantly, because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. Some of the side effects take months to years to develop so constant diligence is needed.

36. Amiodarone causes many horrific side effects that have resulted in its restricted use in the United States including; causing blindness, it causes deposits to form on the cornea of the eyes, a condition in virtually everyone who takes the drug; Amiodarone causes a very disfiguring blue-grey discoloration of the skin, generally in areas of exposure to the sun; Amiodarone often sensitizes the skin to sunlight so that even trivial exposure results in severe sunburns; Amiodarone causes hypothyroidism-low thyroidism, a condition relatively easy to treat with thyroid medication. Some patients develop hyperthyroidism-high thyroid, which is more dangerous and more difficult to treat. Amiodarone can cause liver toxicity; therefore, liver enzymes need to be monitored periodically. Amiodarone can cause severe gastric reflux, caused by a paralysis of the sphincter at the end of the esophagus.

37. The most serious side effect of Amiodarone and the one requiring the FDA-mandated patient Medication Guide is pulmonary toxicity-lung disease. Amiodarone produces two types of lung disease-first, acute pulmonary syndrome which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that rapidly improves once the Amiodarone is stopped. The second type is more dangerous. This condition involves a

gradual, almost unnoticeable stiffening of the lungs that both the doctor and patient overlook until finally severe irreversible lung damage is done. This condition can occur quickly after the taking of the drug or can occur years after the drug has begun. Lung toxicity has been found by the FDA to be 17% and fatalities from pulmonary toxicity have been found to be 10% of those taking the drug. These statistics come from those taking the drug for conditions the drug is not approved for-arterial fibrillation, as well as the ventricular condition it is approved for as a drug of last resort after other treatments have been tried and have failed.

38. Amiodarone never underwent the rigorous randomized trials all other FDA approved drugs other than a few "grandfathered" drugs with long market histories have undergone. Despite repeated requests, demands and even threats from the FDA the manufacturers of Amiodarone and its FDA labeled "brand-names" Wyeth's Cordarone and Upsher-Smith's Pacerone, have never undergone the type of clinical trials that would show its defects or the benefits vs. the risks associated with the drug's use. Despite the economic argument that the patent has expired, or that the costs of testing is too high to justify the investment Amiodarone continues to generate enormous revenues for the drug manufacturers without the public having the protection of FDA randomized clinical trials.

39. The only trials Amiodarone underwent were non-scientific, reporting of a combination of various patient results combined to obtain statistical data that is neither randomized or reliable and which interestingly enough did not even provide the statistical data that has been determined by the FDA to be accurate for the drug and required in the black box labeling of the product. Obviously, this combination of reporting of various patients was non-scientific and cannot serve as the basis for a claim of preemption.

40. Without rigorous, scientific, clinical trials and randomized testing approved by the FDA the reasons for FDA preemption do not exist and cannot be sustained. Neither the so-called "brand names" or the generic versions of the drug offer any protection to the public from the FDA approval process. Since the manufacturers will not undergo FDA approved testing they cannot use the FDA approval process as a shield from liability when sued. None of the reasons articulated by the United States Supreme Court for the protection preemption provides is present with Amiodarone. None of the cost-benefit analysis is present. In addition, none of the regulatory analysis arguments nor any Federalism arguments are present to support preemption.

41. This is not to say the FDA completely disregarded its regulatory or enforcement powers regarding Amiodarone. While no testing justifying preemption was ever performed, when the statistical evidence of the dangers of Amiodarone and its many side effects became known, the FDA repeatedly amended the labeling requirements for Amiodarone, mostly resulting from public pressure and for just the sixtieth time in regulatory history enacted a requirement that the drug manufacturer directly provide the patient a FDA approved "Medication Guide" along with the drug.

42. Due to the failure to conduct required randomized clinical testing by the Defendant and other manufacturers, Plaintiff is not preempted from claiming that Defendant illegally marketed the product for off-label use. Most importantly, Plaintiff is not preempted from claiming Defendant failed to warn of the dangers of the product by failing to provide the FDA required Medication Guide consisting of ***only*** language the FDA approved to go directly to the patient. The failure to provide the FDA Medication Guide is a stronger claim than merely alleging the package insert or labeling fails to inform or warn patients or consumers of the dangers of the product. The

failure to provide each patient a Medication Guide is a direct violation of the FDA's mandate to the manufacturers of the drug intended to warn patients of the very dangers that killed Noel Priest.

C. Cordarone®, Concealment, And The Off-Label Promotional Scheme

43. As noted above, on or about December 24, 1985, drug manufacturer Wyeth introduced Cordarone® into the United States stream of commerce. Wyeth received approval for Cordarone® from the FDA only as a drug of last resort for patients suffering from documented recurrent life-threatening ventricular fibrillation and ventricular tachycardia; and further, only when these conditions would not respond to other available anti-arrhythmic drugs and therapies. Pacerone was introduced by Upsher-Smith in 1998 under the same approval guidelines by the FDA as for Cordarone.

44. The FDA's early specific enforcement actions regarding the marketing and labeling of the drug Cordarone®, include:

a. On or about October 7, 1986: label revision;

b. On or about May 15, 1987: label revision;

c. On or about August 7, 1987: package change;

d. On or about October 28, 1987: manufacturing changes;

e. On or about June 29, 1988: label revision;

f. On or about September 14, 1988: label revision;

g. On or about December 13, 1988: package change;

h. On or about February 2, 1989: label revision;

i. On or about July 28, 1989: formulation revision;

j. On or about August 9, 1990: label revision;

k. On or about August 9, 1990: manufacturing change;

l. On or about April 14, 1994: label revision;

m. On or about October 15, 1995: label revision;

n. On or about June 15, 1998: label revision;

o. On or about January 5, 1999: label revision;

p. On or about October 8, 1999: label revision;

q. On or about December 18, 1999: label revision;

r. On or about September 20, 2002: control supplement;

s. On or about December 18, 2002: label revision;

t. On or about April 30, 2003: label revision;

u. On or about May 6, 2003: label revision;

v. On or about May 21, 2004: label revision.

45. On or about December 15, 1989, and subsequently in 1992, 1998, and thereafter, the FDA sent violation communications to Wyeth regarding the FDA's determination that Wyeth had violated the Act and its implementing regulation by, inter alia, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone®. Wyeth misrepresented Cordarone's® indications and usage, efficacy,

risks, and benefits. Further, Wyeth intentionally failed to submit marketing materials to the FDA in violation of the Act.

46. Upon information and belief, in May of 1995, the Australian Government's Therapeutic Goods Administration (that country's counterpart to the U.S. FDA), issued an Australian Adverse Drug Reactions Bulletin, emphasizing that Amiodarone was appropriate only for use in the treatment of ventricular and supraventricular arrhythmias. Notably, this Bulletin highlighted that "the drug [Amiodarone] is known to have multiple adverse effects, which can involve most organ systems," and again stressed that "Amiodarone is only to be used in patients with serious arrhythmias where there is no safer drug therapy."

47. Upon information and belief, on or about April 29, 1996, the FDA required Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Carcinogenesis;

b. Mutagenesis;

c. Impairment of fertility, pregnancy;

d. Neonatal hypo- or hyperthyroidism.

48. Upon information and belief, the severity of catastrophic adverse reactions, including death, led Wyeth to discontinue production and distribution of Cordarone® in Canada on or about September 10, 1996.

49. Upon information and belief, on or about February 11, 1997, the FDA issued a warning letter to Wyeth regarding Cordarone's® understated or incorrect labeling and warnings

based on the FDA's medical research. Thereafter, on or about April 16, 1997, Wyeth changed its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Loss of vision;

b. Impairment of vision, including optic neuritis, optic neuropathy, corneal lesions, lens opacities, optic disk damage, papilledema, retinal hemorrhage and degeneration, photophobia;

c. Liver injury;

d. Pregnancy complications;

e. Adult Respiratory Distress Syndrome;

f. Angioedema;

g. Mortality.

50. Upon information and belief, in 1998 the FDA issued a Written Request for Pediatric Studies under Section 505A of the Act to Wyeth regarding Cordarone®. Upon information and belief, the basis for this request was that insufficient tests, surveys, and studies had been conducted regarding Cordarone® consumption by pediatric patients, although there was knowledge by Defendants and other drug manufacturers and in the medical community that off-label use of Cordarone® in pediatric patients was being more and more common.

51. Upon information and belief, in 1998 the FDA issued a letter to Wyeth requiring that company to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Mortality (based upon the European Infarct Amiodarone Trial and Canadian Myocardial Infarct Trial);

b. Precautions regarding volatile anesthetic agents for Amiodarone users undergoing surgery;

c. Carcinogenesis;

d. Mutagenesis;

e. Impairment of fertility, pregnancy;

f. Neonatal hypo- or hyperthyroidism.

52. Upon information and belief, Wyeth's sales and promotional practices for Cordarone®, included that on or about December 6-10, 1998, Wyeth sponsored a CME for the 33rd Midyear Clinical Meeting of the American Society of Health-System Pharmacists. This CME was for healthcare providers, including pharmacists, as part of Defendant's ongoing promotion of Cordarone® for off-label purposes. As part of the CME, Wyeth produced and distributed to attendees, a 68-page official looking, peer review-appearing magazine, "The Pharmacist Reporter (July 1999, Vol. 4, No. 5)." This publication was actually a promotional bulletin highlighting Wyeth's goal for Cordarone®: increased off-label use. Among the topics addressed in various articles in "The Pharmacist Reporter," several of which appear to soften, downplay, and/or minimize Cordarone's® devastating side effects, were the following:

a. "An Aggressive Treatment Strategy for Atrial Fibrillation";

b. "Use of Amiodarone in Patients Undergoing Cardiothoracic Surgery";

c. "A Possible New Standard of Care for Prehospital Cardiac Arrest."

53. On or about October 8, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. Clinical pharmacology and pharmokinetics, in that food consumption increases Cordarone's® absorption rate;

b. Geriatric use, whereby clinical studies of Cordarone® in persons 65 and older had not been conducted;

c. Dosage and administration, in that food consumption must be addressed in dosing and loading doses are to be used.

54. On or about January 12, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding Geriatric use, whereby clinical studies of Amiodarone in persons 65 and older had not been conducted.

55. On or about February 12, 1999, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the effects of food consumption on dosage and administration.

56. Wyeth was affected by the February of 2002 Australian Government's Therapeutic Goods Administration (hereinafter "TGA") issuance of an Australian Adverse Drug Reactions Bulletin, alerting healthcare professionals in that country that numerous adverse medical events associated with Cordarone® had been reported to the TGA in 2002 and 2001, including Cordarone-induced pulmonary toxicity and deaths. The TGA warning contained the following important information for healthcare professionals:

> "Although commonly insidious in onset, amiodarone—induced pulmonary toxicity may develop rapidly. The lowest effective dose should be used, and patients should be instructed to report any dysponea or non-productive cough. Amiodarone also has other toxicities including hepatotoxicity which can cause cirrhosis and hepatic failure, cardiovascular effects including bradycardia and tachycardia, skin reactions including photosensitivity and discolouration, neurotoxicity including ataxia and peripheral neuropathy, as well as both corneal deposits and hyper- and hypothyroidism."

57. On or about December 18, 2002, the FDA issued a letter to Wyeth requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding adverse drug interactions with immunosuppressant static drugs, resulting in rhabdomyolysis.

58. On or about December 19, 2002, the FDA issued a warning letter to Wyeth requiring it to correct understated warnings and/or issue new warnings regarding the following:

a. Acute onset (days to weeks) of pulmonary toxicity;

b. Patients having preexisting pulmonary disease have poorer prognosis if pulmonary toxicity develops;

c. Post-marketing reports include possible fatal respiratory disorders (including distress, failure, arrest, ARDS, fever, dyspnea, cough, hemoptysis, wheezing, hypoxia, and pulmonary infiltrates).

59. In 2003, the FDA issued a warning letter to Wyeth, requiring Wyeth to change its labeling, warnings, and packaging for Cordarone®; specifically, adding new warnings or revising minimalist warnings regarding the following:

a. worsened arrhythmia;

b. thyroid abnormalities;

c. drug interactions (protease inhibitors, histamine antagonists, immunosuppressives, antibiotics, cardiovasculars, anti-arrhythmics, anti-hypertensives, anticoagulants);

d. other substance (grapefruit juice, herbal supplements) interactions;

e. electrolyte disturbances; and

f. nursing mothers passing the drug to newborns through breast milk.

60. Optic neuropathy is an under reported adverse side effect of Cordarone®.

61. It was known to Wyeth, that Cordarone® use had resulted in vision loss and permanent blindness.

62. Wyeth had previously been forced by the Canadian Government to change the drug's labeling in Canada.

63. In addition, upon information and belief, Wyeth's pharmaceutical sales and marketing directors encouraged their respective sales representatives to visit physicians' offices throughout the United States to promote and over promote the drug for off-label use, such as atrial fibrillation. Wyeth has realized more than ***three billion dollars*** ($3,000,000,000) in sales for "off-label" uses of Cordarone®.

64. To date, despite changing the warnings and labeling for Cordarone® multiple times over the past 25 years and the requirement for the distribution of Medication Guides to all patients, and knowing of numerous catastrophic injuries caused by Cordarone®, Wyeth continued to understate the drug's nature and adverse risks of catastrophic injury, pulmonary injury and death.

65. Wyeth was on notice, by no later than 1998, that severe damage to the lungs were side effects of the ingestion of Cordarone® which can cause permanent injury and death.

66. In 2003, the FDA sent violation communications to Wyeth regarding the FDA's determination that Wyeth and others had violated the Act and its implementing regulation by, inter alia, disseminating false and misleading materials to physicians and the public without adequate risk information concerning the use of Cordarone® by children and pregnant women. Thereafter, these manufacturers notified physicians to stop prescribing Cordarone® to children and pregnant women because of the serious risk of permanent injuries.

67. Wyeth misrepresented Cordarone's® indications and usage, efficacy, risks, and benefits. Further, Wyeth intentionally failed to submit marketing materials to the FDA in violation of the Act.

68. At all material times, Wyeth and others including Defendant willfully failed and refused to actively and affirmatively monitor Cordarone's® "off-label," unapproved uses insofar that such uses caused catastrophic injuries and death. Wyeth, however, continued to promote Cordarone® for unapproved uses. Such promotion had direct beneficial results for generic manufacturers including Defendant as well.

D. Generic Manufacturers Join and Contribute to a Huge Market for the Illegal Off-Label Use of Amiodarone as a First-Line Treatment for Atrial Fibrillation

69. Wyeth instituted and maintained an active promotional campaign to physicians touting the anti-arrhythmic benefits of Amiodarone. The campaigns were aggressive and, in many situations, focused on the use of the drug as a "first line" atrial fibrillation treatment, and failed to warn prescribing physicians of the known potential dangers associated with Amiodarone toxicity to atrial fibrillation patients. Wyeth's campaigns were so pervasive and effective that for an entire

generation of physicians, the drug wrongfully became a first line therapy for atrial fibrillation because physicians were not warned of many of the potential dangers of the drug.

70. Wyeth's fraudulent and misleading marketing campaigns resulted in warning letters from the FDA to stop Wyeth's false and misleading promotion of the drug that downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.[7] The FDA's letters to Wyeth noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.[8] The purpose of this federal requirement is to protect patients by ensuring drug manufacturers subject prospective uses of their drugs to randomize and well-controlled clinical trials to determine whether the drug is safe and effective for such uses. These requirements are meant to ensure that drug companies like Defendant give physicians and medical personnel trustworthy information so that medications are prescribed appropriately. Defendant supplied the same material with the drugs they sold during this time as Wyeth and not only benefitted from the Wyeth off-label promotion but enlarged the participation by sending so-called education or informational material with the drugs they sold that mimicked the Wyeth off-label campaign.

71. Physicians may still prescribe drugs for unapproved uses. These uses are deemed "off-label" because they have not been approved by the FDA. A pharmaceutical company is also permitted to disseminate certain information about off-label uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing

[7] Warnings by the FDA to Wyeth began as early as 1988. Http://www.mcclatchydc.com/2003/11/04/28118/fda-oversight-of-off-label-drug.html

[8] *See* 21 U.S.C. §§ 331(d), 352(f), and 355

materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . . necessary to provide objectivity and balance."[9] This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate.[10] A drug manufacturer's dissemination of information in violation of these provisions – any deviation is a violation – also violates the FDCA and regulations promulgated thereunder.[11]

72. In 1998, Upsher-Smith received FDA approval to market, manufacture, and sell the anti-arrhythmic heart medication Pacerone as a bioequivalent and therapeutically equivalent to the Cordarone® tablets from Wyeth Ayerst. The drug was therefore subject to the same advertising, marketing, and promotional requirements set forth by the FDA for Wyeth Ayerst in their advertising, marketing, and promotion of the drug Cordarone®. As with all generic approvals, Upsher-Smith was required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings, and medication guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.[12] Likewise, Sandoz benefitted and adopted the off-label uses and materials provided by Upsher- Smith and marketed the Amiodarone sold without the FDA mandated Medication guides and without responding to the FDA requirements or regulations.

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[9] A pharmaceutical company is permitted to disseminate certain information about off-label uses, but such dissemination must adhere to strict requirements. For instance, the manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA prior to dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, "additional objective and scientifically sound information . . . necessary to provide objectivity and balance." 21 U.S.C. § 360aaa, *et seq.*

[10] 21 U.S.C. § 360aaa

[11] 21 U.S.C. § 331(z)

73. Defendant Sandoz and Novartis Pharmaceuticals Corporation ("Novartis") received approval for the manufacture, marketing, sale and distribution of the generic formulation Amiodarone hydrochloride in 1998.[12] As with all generic bioequivalent approvals, Defendant Sandoz and Novartis were required by the FDA to provide patients prescribed the drug with all FDA approved labels, warnings and Medication Guides with information exactly as required of the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.[13]

E. The FDA Requires Plain-English Medication Guides for Amiodarone to Replace Package Inserts

74. Each manufacturer who ships a container of drug product for which a Medication Guide is required is responsible for ensuring that Medication Guides are available for distribution to patients.[14] Defendant is a manufacturer as defined by the FDA. The FDA has recognized that "it is important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications." The FDA has expressed concern at the failure of drug manufacturers in distribution of the Medication Guides and that "the current Medication Guide program is too cumbersome and that it lacks a standard distribution system."

75. The National Consumer Pharmacy Association has identified the failure of manufacturers to ensure the distribution of Medication Guides as a significant safety issue and called on the FDA to "enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce

[12] The approval letter noted on the FDA database is addressed to Eon Labs Manufacturing, Inc. and dated December 23, 1998. Http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/75315ltr.pdf.
[13] *See* 21 U.S.C. § 355(j)(2)(A)(v); § 355(j)(4)(G).
[14] *See* 21 CFR § 208.24.

Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product.[15] Noel Priest did not receive a Medication Guide.

76. According to the FDA, the medication guide replaces the previous "package inserts" or any other means by which the manufacturers may attempt to warn consumers of the effects of the drugs Cordarone or Amiodarone. Drugs like those sold to Noel Priest are therefore "mis-labeled" and illegally sold. Strict liability is imposed on the sellers of illegal drugs. The need for the Medication Guide was so great the FDA not only replaced package inserts, but "all" other means of providing information to consumers of the dangers of the drug. The manufacturers are responsible for the consumer receiving the FDA approved medication guide with EACH Amiodarone prescription. A "non-delegable" duty, and one that cannot be accomplished by other means. Any addition or subtraction renders the Sandoz drug illegal as sold to Noel Priest. Sandoz is to this day selling an illegal drug including package inserts with the drug or "adding to" the FDA Medication Guide.

F. Noel Priest Needlessly Dies Because of Defendant's Actions

77. Plaintiff's decedent Noel Priest died from Amiodarone toxicity induced pulmonary fibrosis lung disease. Prior to taking Amiodarone, Noel Priest was not in a medical situation of "last resort" as to the management of any heart condition.

78. On or about, June 30, 2013, Plaintiff's decedent, Noel Priest, sought treatment for an irregular heartbeat in the emergency room at Arlington Memorial Hospital. Mr. Priest was

[15] Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, RPh; Bryan Ziegler, PharmD, MBA.

examined and treated by, Anees U. Saleemi, M.D., who admitted Mr. Priest, as an inpatient, to Arlington Memorial Hospital. Mr. Priest was diagnosed, Dr. Saleemi prescribed the drug Amiodarone, an "off label" use of this drug. On July 2, 2013, Mr. Priest was released from Arlington Memorial Hospital with a prescription for 400mg tablets of Amiodarone and instruction to continue ingesting one tablet each morning with breakfast. On information and belief, his prescribing physician was influenced by the Amiodarone off-label marketing and promotion conducted by Sandoz, Wyeth, and other manufacturers.[16] This marketing and promotion, conducted over a period of many years, created a market for Amiodarone – a toxic drug – in which approximately 90% of the prescriptions are for off-label use. On information and belief, this marketing and promotion influenced the prescribing physician to prescribe Amiodarone as a first-line medication for Noel Priest's heart condition, despite the fact that the FDA has not authorized such use, and despite the fact that the FDA's "special" authorization is for a "last chance" medication for a much more serious heart condition.

79. Noel Priest filled the prescription at the Kroger Pharmacy at 514 Carrier Parkway in Grand Prairie, Texas, and ingested the Amiodarone according to instructions.[17] He was not aware that his use of the medication was for an "off-label" use and, as noted above, he was not in a situation of last resort as to his heart condition. Noel Priest's prescription was for an "off-label" use of Amiodarone.

80. The Amiodarone tablets Noel Priest received in connection with all of his Amiodarone prescriptions were each marked with E and the number 144 and NDC # 51862015630

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[16] This evidence, like much of the evidence needed to support Plaintiff's allegations and causes of action, is unattainable by Plaintiff, and likely by any plaintiff in similar circumstances, absent the authority to pursue discovery from Defendant and others.

[17] Kroger Pharmacy label RX# 6125248 of Noel Priest.

and 00185014460 which identified the tablets as manufactured, marketed and distributed by Sandoz.[18] The Amiodarone ingested by Noel Priest was the generic version of Wyeth's Cordarone®.

81. The Kroger Pharmacy providing Noel Priest with Amiodarone did not provide him with the Medication Guide.[19] Kroger did not provide it because Sandoz did not provide Medication Guides to Kroger, rendering the drug illegal for sale. According to the Kroger Pharmacy in question, Sandoz did not provide Kroger with Medication Guides for Amiodarone at time Kroger filled Mr. Priest's prescriptions. In fact, the earliest manufacturer-provided Medication Guide the pharmacy could identify was dated March 2015, twenty months after Mr. Priest first filled his prescription, and there is no indication that the Medication Guide the pharmacy has on file now was provided by Sandoz. Sandoz was responsible for ensuring that the Medication Guide was provided to Noel Priest. Had he been provided the Medication Guide, he would have been aware of the serious lung related side effects that could lead to death as well as other issues and he would not have taken Amiodarone.

82. Noel Priest was also not provided appropriate and up-to-date warning labels that were required to be given in order to warn him of the serious side effects of Amiodarone. Sandoz was responsible for ensuring that the appropriate warning labels were provided to Noel Priest. Had he been provided the up-to-date warning labels, he would have been aware of the serious lung-

[18] *Id.*
[19] The FDA requires that Medication Guides be issued with certain prescribed drugs and biological products when the Agency determines that certain information is necessary to prevent serious adverse effects; patient decision-making should be informed by information about a known serious side effect with a product, or patient adherence to directions for the use of a product are essential to its effectiveness. http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm.

related side effects that could lead to death as well as other issues and he would not have taken Amiodarone.

83. The serious side effects outlined in the Medication Guide, all of which Noel Priest experienced after taking Amiodarone, included lung damage, shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.[20]

84. Because he was not provided a Medication Guide, Noel Priest did not know that Amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then when "other treatments did not work or were not tolerated."[21] He did not know that any other use such as the use for his atrial fibrillation was considered to be "off-label" and Noel Priest did not know of the corresponding dangers associated with such uses.

85. Because he was not provided a Medication Guide, Noel Priest did not know "the medicine stays in your body for months after treatment is stopped."[22] The effects of Amiodarone are long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin and confers a high volume of distribution and a long half-life; the amount of time it takes for one-half of an administered drug to be lost through biological processes (metabolism and elimination). Because of this long half-life, Amiodarone's dangerous properties continue to cause injuries in patients long after they have ceased using the drug, including, serious pulmonary injuries. This information was unknown to Noel Priest.

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[20] Medication Guide for Amiodarone HCI. http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf.
[21] *Id*.
[22] *Id*.

86. Each manufacturer who ships a container of drug product for which a Medication Guide is required is responsible for ensuring that Medication Guides are available for distribution to patients.[23] Defendant is a manufacturer as defined by the FDA. The FDA has recognized that "it is important that patients receive appropriate risk information in the form of Medication Guides in order to make informed decisions about certain prescribed medications." The FDA has expressed concern at the failure of drug manufacturers in distribution of the Medication Guides and that "the current Medication Guide program is too cumbersome and that it lacks a standard distribution system."

87. The National Consumer Pharmacy Association has identified the failure of manufacturers to ensure the distribution of Medication Guides as a significant safety issue and called on the FDA to "enforce current FDA MedGuide regulations holding manufacturers accountable for providing Medication Guides in sufficient number or the means to produce Medication Guides in sufficient number, to permit the authorized dispenser to provide a Medication Guide to each patient who receives a prescription for the drug product.[24] Noel Priest did not receive a Medication Guide.

88. In the summer of 2013, Noel Priest began to experience many of the symptoms outlined in the Medication Guide to include shortness of breath, muscle weakness, decreased appetite, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression.

[23] *See* 21 CFR § 208.24

[24] Use of Medication Guides to Distribute Drug Risk Information to Patients, Colleen Brennan, RPh; Bryan Ziegler, PharmD, MBA.

89. At the time his cardiologist prescribed Noel Priest to take Amiodarone for his heart condition, Mr. Priest lead an extremely active lifestyle that still included taking care of all his own yard and house work. Mr. Priest travelled often with family and friends. Mr. Priest had several grandchildren and often had family reunions where he engaged in many sports with his children and grandchildren. He had an incredible appetite yet remained trim, fit, and active. He did all his own yard work and household chores. Mr. Priest also participated in many activities with his wife and her younger friends. No matter how rigorous the activity might have appeared, Mr. Priest did not hesitate to participate right up until the summer of 2013 when he was prescribed Amiodarone.

90. Not long after being prescribed Amiodarone, Noel Priest began to suffer serious symptoms that directly affected the quality of his life. Mr. Priest started to feel dizzy and not well and began to have problems with his breathing. Mr. Priest's condition had worsened considerably, and he was feeling miserable. He had shortness of breath, dizziness and a loss of appetite, and he was losing his strength as well. His muscles seemed to be deteriorating. Mr. Priest began losing his balance and falling. Moreover, he was complaining that he could not swallow and was losing weight as well. From the short time he took Amiodarone, Noel Priest went from an active able bodied man who took care of his own responsibilities, to a man who was hospitalized, unable to eat, unable to talk, and eventually unable to write or communicate at all while his family watched his drastic decline.

91. Noel Priest died at 8:28 PM on March 17, 2014. At the time of his death, Noel Priest was a 79-year-old resident of Grand Prairie, Texas. Amiodarone toxicity induced pulmonary fibrosis lung disease was his final diagnosis.

G. Facts Common To All Counts

92. At all material times, Defendant has had actual or constructive knowledge that Amiodarone cause and contribute to severe and disabling medical conditions and death, such as those experienced by Noel Priest, including, without limitation, the following: pulmonary toxicity, pulmonary fibrosis, hepatic damage and failure, neurotoxicity, neonatal hypothyroidism, birth defects, optic neuritis, toxic optic neuropathy, blindness, peripheral neuropathy, heart damage and failure, hypotension, serious exacerbation of arrhythmias, and congestive heart failure.

93. Upon information and belief, Defendant has received information concerning more than one thousand deaths resulting from the use of Amiodarone.

94. Upon information and belief, Defendant has received information concerning cases of severe medical conditions resulting from the use of Amiodarone, including, without limitation, pulmonary toxicity, pulmonary fibrosis, lung damage (as experienced by Noel Priest), hepatic damage and failure, neurotoxicity, peripheral neuropathy, neonatal hypothyroidism, optic neuritis, toxic optic neuropathy, blindness, serious exacerbation of arrhythmias, and congestive heart failure such as that experienced by Plaintiff's decedent, Noel Priest.

95. Healthcare providers, as well as patient-consumers reported these events, upon information and belief, directly to the Sandoz.

96. In addition to these direct notices of adverse events, the FDA had, and continues to have, in effect, an adverse reaction surveillance system for all regulated drugs, including Amiodarone, called the Adverse Event Reporting System (AERS).

97. Upon information and belief, the AERS has placed Defendant on notice of numerous instances of catastrophic injuries caused by ingestion of Amiodarone.

98. At all material times, Defendant failed to disclose to the FDA, healthcare professionals, consumers, or Noel Priest, of the information they possessed concerning the incidents and actual adverse medical events, injuries, and deaths suffered by Amiodarone users. Instead, upon information and belief, Defendant actively promoted, or piggy-backed the promotional efforts of innovator drug manufacturer Wyeth, Amiodarone for "off-label," unapproved uses as described herein through various means, including, but not limited to, the following:

a. Direct-to-physician and direct-to-pharmacist promotion through sales representatives;

b. Promotion through funding and manipulation of so-called "educators" who organize and arrange continuing medical education (CME) courses for physicians and pharmacists;

c. Formulation of unlawful conspiracies with certain medical marketing and medical "education" entities to promote – without appearing to promote – off-label uses;

d. Sponsorship and funding of the production of CME materials;

e. Cultivation and development of so-called "opinion leaders" in local medical communities and support for the careers and research of those physicians, pharmacists, and researchers who advocate off-label uses;

f. Sponsorship of journal supplements and symposia on off-label uses for Amiodarone;

g Placing (through sponsorship of limited trials, studies, and surveys) of medical literature databases showing positive effects (already established) on risk factors with the twin purposes of overwhelming any independent study showing negative effects on different risk factors, and causing earnest but time-crunched physicians to be impressed with the sheer quantity of favorable (but redundant) studies on Medline, or medical library, search;

h Media advertisements and brochures, some of which were disguised as "educational materials";

i. Various other forms of marketing and promotion.

99. Upon information and belief, in accepting the benefits Wyeth efforts in promoting "off-label" uses of Amiodarone by sponsoring CME conferences and materials, journal supplements, redundant trials, and the work and careers of favorably disposed opinion leaders, Defendant would sometimes escape disclosure for any role at all in the presentation of its desired view.

100. Additionally, upon information and belief, Sandoz and/or its agents' pharmaceutical sales representatives actively promoted their generic Amiodarone in the stream of commerce for the "off-label" uses openly promoted by Wyeth.

101. On information and belief, at all materials times, despite FDA warnings and thousands of adverse patient experiences, Defendant continued its fraudulent marketing, promotional, and sales practices from 1999 through the present date.

102. On information and belief, at all materials times, Defendant concealed information about catastrophic injuries and death, and thousands of serious adverse medical events from the FDA, health care professionals, and consumers, including Noel Priest.

103. At all material times, the Amiodarone manufactured and/or supplied by Defendant was and is unaccompanied by the FDA-mandated Medication Guide.

104. Although Defendant knows, should have known, and currently knows that the majority of patients consuming Amiodarone are senior citizens, including those aged 55 and over such as Noel Priest, Defendant has failed and refused to conduct testing, studies, surveys, and/or report the results of same regarding Amiodarone use in this age group.

105. At all material times, the Amiodarone manufactured, distributed, and/or supplied by Defendant was defective due to inadequate post-marketing warning and instruction because, after Defendant knew or should have known of the risk of injury from Amiodarone, especially in

"off-label" use, Defendant failed to provide adequate and required warnings to physicians, users or consumers of Amiodarone, including the Noel Priest, and continued to aggressively sell Amiodarone, including for "off-label" use.

106. At all material times, while Defendant, and the other manufacturers, concealed this adverse event information, they simultaneously engaged in a massive and fraudulent marketing and promotional scheme in which they aggressively and fraudulently promoted Amiodarone for uses never authorized by the FDA. In fact, Sandoz, Wyeth, and other manufacturers marketed, promoted, and "pushed" Amiodarone, not as a drug of last resort, but as a drug suitable as an initial therapy and to treat non-life-threatening heart conditions.

107. At all material times, Sandoz, Wyeth, and other manufacturers, also promoted Amiodarone for heart conditions less severe than life-threatening ventricular arrhythmia (the only purpose for which the drug originally received FDA approval).

108. Sandoz, Wyeth, and other manufacturers engaged in a conspiracy of silence regarding "off-label" use, choosing to market and promote the drug for "off-label" use, and then feigning ignorance before the FDA, health care providers, and consumers. They failed and refused to conduct thorough testing on the side effects, despite knowing that their scheme to promote the drug for "off-label" uses had been, and continues to be, successful.

109. Sandoz, Wyeth, and other manufacturers have engaged in this calculated and coordinated silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Amiodarone, and did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Noel Priest.

110. At all material times, Sandoz's, Wyeth's and other manufacturers' affirmative misrepresentations and omissions have so infected the market in the United States that physicians and consumers relied on their misrepresentations and omissions, respectively, to the detriment of their patients and themselves.

111. Under increased FDA scrutiny and mandates, Sandoz, Wyeth, and other manufacturers have been forced to correct and change their warning labels, and add new warnings, for Amiodarone's adverse side effects about which they knew long before being required to make such changes. Defendant should be required to follow the FDA mandate and "only" provide the FDA Medication Guide warning against off-label use, and use of the drug Amiodarone other than as a drug of last resort.

112. At all material times, Sandoz's Wyeth's, and other manufacturers' deception, concealment, and fraudulent marketing and promotion has been so pervasive throughout the United States, that prescribing physicians and consumer patients during the relevant time period still believe that Amiodarone is an acceptable initial, secondary, or otherwise early-stage anti-arrhythmic intervention. These deceptive techniques served (and continue to serve) Defendant and other manufacturers in several ways, including: (1) instilling Defendant's desired view about the drug's "off-label" uses among health care providers; (2) Defendant hoped that, by concealing its agency in these activities, it would escape the legal ramifications of its unlawful promotional activities; and (3) boost Defendant's profits from the drug.

113. At all material times, Defendant owed a duty to the health care providers, consumer patients, and Noel Priest, to engage in honest and non-deceptive practices; exercise due care under the circumstances, to exercise due care in the marketing, promotion, sale, and distribution of

Amiodarone; to comply with federal guidelines, rules, and regulations; and/or to sell and distribute the drug in accordance with FDA restrictions.

114. At all material times, Defendant marketed Amiodarone as having approval, characteristics, uses, and benefits that the drug did not have.

115. At all material times, Defendant did adopt the design, creation, testing, development, labelling, packaging, manufacturing, marketing, promotion, advertising, distribution, selling, warnings, and/or otherwise caused the product to be placed into the stream of commerce, and ultimately to be ingested by Noel Priest.

116. At all material times, Defendant willfully failed and refused to actively and affirmatively monitor Amiodarone's "off-label," unapproved uses insofar that such uses caused catastrophic injuries and death. Defendant however, continued to sell Amiodarone for unapproved uses.

117. At all material times, Sandoz, Wyeth, and other manufacturers engaged in a continuing course of fraud, concealment, material nondisclosure, omission, and negligent promotion upon Plaintiff which prevented Plaintiff from knowing or having reason to know of Defendant's misconduct.

V. Causes of Action

A. Wrongful Death

118. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

119. The death of Noel Lajoie Priest was directly and proximately caused by the negligent actions of the Defendant as related to the manufacture, marketing, distribution and sale of Amiodarone as described herein.

B. Gross Negligence

120. Plaintiff incorporates all previous paragraphs.

121. Despite the FDA including requirements for "Black Box" warnings about the dangers of Amiodarone and its brand name equivalent, the FDA recognized that too many patients were dying from ingesting this drug. The manufacturers were hiding the "Black Box" on package inserts that were forty to fifty pages, included the chemical make-up of the drug and were never read or contained in the PDR (Physician's Desk Reference) and physicians had been influenced more by the drug companies marketing and sales scheme, than the warnings. Patients were not being told of the drugs dangers and were dying.

122. For only the 60th time in its history of drug approval and regulation making, the FDA made a rule making decision requiring that "THE MANUFACTURER" of the brand name or generic drug Amiodarone provide to the patient ingesting the drug a MEDICATION GUIDE with FDA approved warning that could not be added to or subtracted from by the drug companies.

123. Despite the FDA requirements that the drug companies provide the patients medication guide with FDA written material with their Amiodarone prescription, no Medication Guide was provided to Noel Priest by Defendant.

124. If Noel Priest had been provided the Medication Guide he would not have taken Amiodarone for a non-life threatening, non-last resort condition – atrial fibrillation, and he would still be alive today.

125. According to the Kroger Pharmacy, Defendant was not providing them or the patients with Medication Guides at the time of the events made the basis of this complaint.

Defendant is guilty of gross negligence for failure to provide the FDA-required Medication Guide.

126. The failure to provide the Medication Guide is a direct and proximate cause of Plaintiff's damages, and also warrants punitive damages.

C. OFF-LABEL MARKETING

127. Plaintiff incorporates all previous paragraphs.

128. Upon information and belief, ninety (90%) percent of the Amiodarone/Cordorone prescriptions written in the United States are written for "arterial-fibrillation," a non-FDA approved use of the drug. When a drug is prescribed by a number of physicians for a non-approved condition, courts can look at the percentage of prescriptions written for the non-FDA condition in order to allow discovery on the issue of off-label promotion.

129. The percentage (90%) of prescriptions of Amiodarone/Cordorone written for non-life-threatening conditions – for a drug with a 10% fatality rate and 17% toxicity rate – is astounding, and it is beyond belief that Defendant was unaware of this. Without off-label promotions, schemes or encouragement, it is inconceivable that caring physicians would continuously write these prescriptions, not only subjecting their non-life-threatened patients to death from the drug but to a *horrific* death, one caused by "Amiodarone toxicity" or pulmonary fibrosis where the patient is unable to breath, coughs, wheezes, struggles to catch their breath or get enough air into their lungs and eventually for humanitarian reasons is placed on morphine until they stop breathing.

130. Plaintiff contends that the off-label use of Amiodarone was promoted by Sandoz and the other drug manufacturers illegally, but in such a manner as to escape FDA regulation. Despite repeated admonitions by the FDA and continuous label changes, the FDA's only solution to the problem was adoption of the required Medication Guide to replace the package inserts, direct physician marketing, and other communication means controlled by the drug industry.

131. On information and belief, the off-label marketing and promotion of Amiodarone by Defendant proximately caused Noel Priest's horrific death. Mr. Priest's physician, Dr. Anees U. Saleemi, like the other doctors writing prescriptions for Amiodarone for use as a first line drug for arterial fibrillation, was influenced by Defendant's, and other manufacturers', long term and successful promotional efforts, and those efforts likely affected his decision to prescribe Amiodarone to Mr. Priest. Because of the secrecy in the drug manufacturing industry, given the billions of dollars at stake, and the likely related lack of whistleblowers, Plaintiff, and those similarly situated, must be granted the right to pursue discovery to support their claims. Otherwise, Sandoz, and other manufacturers, will escape liability not because they are not liable, but because Plaintiff was unable to access the door to justice.

D. SANDOZ'S FAILURE TO PROVIDE THE MEDICATION GUIDE RENDERS SANDOZ'S SALES OF AMIDRONE ILLEGAL, AND SANDOZ'S SALES THEREFORE CONSTITUTED NEGLIGENCE PER SE

132. Plaintiff incorporates all previous paragraphs.

133. FDA regulations required Defendant to provide each patient prescribed Defendant's Amiodarone with a Medication Guide, and nothing else. By failing to provide a Medical Guide Defendant rendered the sale of its Amiodarone to Plaintiff (and others) illegal, and

is guilty of negligence per se. Defendant's negligence per se is the proximate cause of Plaintiff's damages, and constitutes gross negligence, allowing for punitive damages.

VII.
DEMAND FOR JURY TRIAL

134. Plaintiff in the above-styled case hereby demands a trial by jury.

VIII.
PRAYER

WHEREFORE, Plaintiff demands judgment against Defendant for compensatory and punitive damages, together with applicable interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

By: ___/s/ *Jay C. English*_________
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CERTIFICATE OF SERVICE

I hereby certify that on the 10th day of February, 2016, I electronically filed the foregoing document with the Clerk of the Court for the U.S. District Court, Western District of Texas, using the electronic case filing system of the Court. The electronic case filing system will send a "Notice of Electronic Filing" to the following attorneys of record.

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